Message

From: Charlotte Sanson [charlotte.sanson@bayer.com]
Sent: 6/12/2017 6:03:21 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Schaible, Stephen [Schaible.Stephen@epa.gov]; Miller, Wynne [Miller.Wynne@epa.gov]; Pease, Anita [Pease.Anita@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]
CC: George Sabbagh [george.sabbagh@bayer.com]
Subject: RE: Topics for Discussion - Upcoming Meeting with Bayer Regulatory Teams from US & Canada

Hi Rick,

Thanks for the follow-up. There is no set format, and we are very flexible. To best utilize time, we can provide your bios to the participants in advance of your arrival. I propose that each of you would introduce yourself and describe your group's function (in whichever order you wish). After that round, you can address the questions below in whatever order makes sense for you, and I expect the participants will raise further questions during the session. We'll finish with a final Q&A. Would that work well for you?

The registration team members interact most directly with RD, PRD, BEAD and PRIA staff, hence the reasoning for our initial invitation. While our Environmental Safety and Human Safety experts will not participate in this meeting, Marietta and Dana are most welcome to join to complete the OPP conventional chemicals overview.

As FYI, the Westin Hotel has informed us that the meeting room is **Crystal V&VI**.

We greatly appreciate everyone's time and preparation. Please advise if further information or clarification would be helpful.

Freundliche Grüße / Best regards,

Charlotte Sanson
VP, Regulatory Affairs & Compliance, Crop Science

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From: Keigwin, Richard [mailto:Keigwin.Richard@epa.gov]
Sent: Monday, June 12, 2017 7:39 AM
To: Charlotte Sanson; Goodis, Michael; Guilaran, Yu-Ting; Schaible, Stephen; Miller, Wynne; Pease, Anita; Echeverria, Marietta; Vogel, Dana
Cc: George Sabbagh
Subject: RE: Topics for Discussion - Upcoming Meeting with Bayer Regulatory Teams from US & Canada

Thanks Charlotte. How structured will the session be next week? I'm just trying to think about how we can organize ourselves on our end to make it as productive as possible. I'd also like Marietta Echeverria and Dana Vogel to participate – that way you have the entire OPP matrix for conventionals participating.

Here's my bio.

Just a reminder that there is a slight chance that I won't be able to participate. Unfortunately, I won't know until late Monday evening (6/19).

From: Charlotte Sanson [mailto:charlotte.sanson@bayer.com]
Sent: Wednesday, June 07, 2017 1:20 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Guilaran, Yu-Ting <Guilaran.Yu-Ting@epa.gov>; Schaible, Stephen <Schaible.Stephen@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>
Subject: Topics for Discussion - Upcoming Meeting with Bayer Regulatory Teams from US & Canada

Thank you for joining Bayer's North America Regulatory Affairs meeting on June 20th, at the Westin Crystal City starting at 9:30 a.m. and ending by noon (I will follow up later with the conference room location). The group includes our US and Canadian registration teams (approximately 25 people), who have submitted suggested topics/questions, listed below, that you may cover during this discussion; no doubt additional questions will arise during the session. Please note that this is an informal and interactive format, presentation slides are not necessary (although we will have a projector set up for our use throughout the day and thus will be available). Also, if you would please plan to spend a little time describing your/team's function at the beginning. The idea is for our staff to get to know OPP better, the challenges you encounter and understand how we can contribute to the overall success of the Program.

Lastly, if you would please forward a brief bio of yourself to George Sabbagh (copied here) that he can use for introduction purposes.

We very much appreciate you taking the time to meet with us!

Suggested Topics/Questions:

- What are the biggest challenges facing OPP?
- What are your priorities for 2017-2018?
- What does success look like for you?
- What is the impact of the President's proposed budget on your programs and activities?
- How would you describe the level of collaboration with PMRA? How will budget cuts impact this interaction?
- What is the timing of EPA's response to comments received for regulatory reform? What is your process for addressing the submitted comments?
- How is the Agency implementing the new Administration's rule requiring agencies to repeal two regulations for every new directive issued?

- What is the status of PRIA 4?
- What are the primary issues that trigger renegotiation of PRIA decision dates?
- How do PRD and RD coordinate on active ingredient specific issues and on overall process?
- What is the status of the Herbicide Resistance Management policy?
- What is the Agency's perspective on how evolving digital technologies will impact regulations in the future?
- What kinds of technologies are you interested in that might be of benefit to address environmental issues/concerns?
- In the US, the approach to environmental regulation (e.g., ESA) has evolved in a piecemeal fashion, resulting in a fragmented network of various Agencies with limited resources to carry out their missions. What would a more integrated collaborative approach look like?
- For Joint Reviews, what do you see as the benefits, drawbacks, and suggestions to improve the process?
- What do you see as the future of the Regulatory Cooperation Council (RCC) with regard to the new Administration?
- There are active ingredients undergoing the EU renewal process for which MRL's will be reduced to a default of 0.01 ppm, resulting in a trade flow issue. Is EPA planning to work with the EU to address trade barriers that can result from EU cancellation of products that are on the market?
- For a number of our products, no or default tolerances exist in the US due to no residues, or residues below LOQ. Some importing countries, such as those in the Asia Pacific region, do not establish import MRLs for these uses, leading to trade barriers. What is being done to address these situations?

Freundliche Grüße / Best regards,

Charlotte Sanson
VP, Regulatory Affairs & Compliance, Crop Science

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Charlotte,

See the list of questions from the Crop and ES teams below.

Here is the list from ES:

From: George Sabbagh
Sent: Friday, June 02, 2017 2:00 PM
To: Karen Shearer
Subject: FW: NARA meeting

Here is the list from Crop:

-----Original Message-----
From: Charlotte Sanson
Sent: Tuesday, May 30, 2017 12:48 PM
To: George Sabbagh; Karen Shearer
Subject: NARA meeting

Just a reminder to please gather questions/topics from your teams to forward to our EPA and USDA visitors for the NARA meeting. Would like to forward by Monday.

Thanks!

Best regards,

Charlotte Sanson
VP Regulatory Affairs and Compliance
Bayer Crop Science Division

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